FEB 2 3 2007

510(k) Summary for
Dimension Vista™ APOAI Flex® reagent cartridge
Dimension Vista™ APOB Flex® reagent cartridge
Dimension Vista™ Apolipoprotein Calibrator
Dimension Vista™ Apolipoprotein Control

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: k063608

1. Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation:

Manufacturer: Dade Behring Marburg GmbH
Emil-von-Behring Str. 76
35041 Marburg, Germany

Contact Information: Dade Behring Inc.
P.O. Box 6101
Newark, Delaware 19714-6101
Attn: Kathleen Dray-Lyons
Tel: 781-826-4551
Fax: 781-826-2497

Preparation date: February 6, 2007

2. Device Name: Dimension Vista™ APOAI Flex® reagent cartridge
Dimension Vista™ APOB Flex® reagent cartridge
Dimension Vista™ Apolipoprotein Calibrator
Dimension Vista™ Apolipoprotein Control

Classification: Class I; Class II; Class I (reserved)
Product Code: MSJ; JIX; JJY
Panel: Clinical Chemistry (75)

3. Identification of the Legally Marketed Device:

Dade Behring N Antisera to Human Apo A-1 – K860894
Dade Behring N Antisera to Human Apo B – K860894
Dade Behring Apolipoprotein Standard Serum – K041870
Dade Behring Apolipoprotein Control Serum CHD – K993310

4. **Device Description:**

Dimension Vista™ APOAI and APOB Flex® reagent cartridges:
Proteins contained in human body fluids form immune complexes in an immunochemical reaction with specific antibodies. These complexes scatter a beam of light passed through the sample. The intensity of the scattered light is proportional to the concentration of the respective protein in the sample. The result is evaluated by comparison with a standard of known concentration.

Dimension Vista™ Apolipoprotein Calibrator:
APO CAL is a multi-analyte, lyophilized, human serum based product containing apolipoprotein A-I and apolipoprotein B.

Dimension Vista™ Apolipoprotein Control:
APO CON is a multi-analyte, lyophilized, human serum based product containing apolipoprotein A-I and apolipoprotein B.

5. **Device Intended Use:**

Dimension Vista™ APOAI Flex® reagent cartridge:
The APOAI method is an *in vitro* diagnostic test for the quantitative determination of apolipoprotein A-I in human serum, heparinized plasma or EDTA plasma on the Dimension Vista® System. Measurements of apolipoprotein A-I aid in the diagnosis and treatment of lipid disorders, various liver and renal diseases and in the assessment of risk for atherosclerosis and cardiovascular disease.

Dimension Vista™ APOB Flex® reagent cartridge:
The APOB method is an *in vitro* diagnostic test for the quantitative determination of apolipoprotein B in human serum, heparinized plasma or EDTA plasma on the Dimension Vista® System. Measurements of apolipoprotien B aid in the diagnosis and treatment of lipid disorders, various liver and renal diseases and in the assessment of risk for atherosclerosis and cardiovascular disease.

Dimension Vista™ Apolipoprotein Calibrator:
The APO CAL is an *in vitro* diagnostic product for the calibration of the apolipoprotein A-I (APOAI) and apolipoprotein B (APOB) methods on the Dimension Vista® System.

Dimension Vista™ Apolipoprotein Control:
APO CON is an assayed intralaboratory quality control for assessment of precision and analytical bias in determination of apolipoprotein A-I (APOAI) and apolipoprotein B (APOB) on the Dimension Vista® System.

6. **Medical device to which equivalence is claimed and comparison information:**
Dimension Vista™ APOAI and APOB, like Dade Behring N Antisera to Human Apolipoprotein A-1 and Apolipoprotein B are *in vitro* diagnostic tests for the quantitative measurement of apolipoprotein A-I and apolipoprotein B in human serum.

7. Device Performance Characteristics:

The Dimension Vista™ APOAI and APOB assays were compared to the Dade Behring N Antisera to Human Apo A-1 and Apo B assays on the BN ProSpec® System by evaluating serum samples with concentrations ranging from 0.61 g/L to 5.10 g/L for APOA1 and 0.38 g/L to 3.81 g/L for APOB. Regression analyses of these results yielded the following equations.

Method Comparison Study

Comparative Method	n	Slope	Intercept	Correlation Coefficient
N Antisera to Human Apo A-1 on the BN ProSpec®	72	1.007	-0.038	0.997
N Antisera to Human Apo B on the BN ProSpec®	77	1.011	-0.004	0.995

8. Conclusion:

These studies demonstrate correlation and equivalent performance between the Dade Behring N Antisera to Human Apo A-1 and Apo B assays and the Dimension Vista™ APOAI and APOB assays.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Kathleen Dray-Lyons
Dade Behring, Inc.
P.O. Box 6101
Newark, DE 19714-6101 US

FEB 2 3 2007

Re: k063608
Trade/Device Name: Dimension Vista™ APOA1 Flex® reagent cartridge
Dimension Vista™ APOB Flex® reagent cartridges
Dimension Vista™Apolipoprotein Calibrator
Dimension Vista™Apolipoprotein Control
Regulation Number: 21 CFR 862.1475
Regulation Name: Lipoprotein test system
Regulatory Class: Class II
Product Code: MSJ, JIX, JJY
Dated: December 01, 2006
Received: December 04, 2006

Dear Ms. Dray-Lyons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications Statement

Device Name: Dimension Vista™ APOAI Flex® reagent cartridge
Dimension Vista™ APOB Flex® reagent cartridge
Dimension Vista™ Apolipoprotein Calibrator
Dimension Vista™ Apolipoprotein Control

Indications for Use:

Dimension Vista™ APOAI Flex® reagent cartridge:
The APOAI method is an *in vitro* diagnostic test for the quantitative determination of apolipoprotein A-I in human serum, heparinized plasma or EDTA plasma on the Dimension Vista® System. Measurements of apolipoprotein A-I aid in the diagnosis and treatment of lipid disorders, various liver and renal diseases and in the assessment of risk for atherosclerosis and cardiovascular disease.

Dimension Vista™ APOB Flex® reagent cartridge:
The APOB method is an *in vitro* diagnostic test for the quantitative determination of apolipoprotein B in human serum, heparinized plasma or EDTA plasma on the Dimension Vista® System. Measurements of apolipoprotein B aid in the diagnosis and treatment of lipid disorders, various liver and renal diseases and in the assessment of risk for atherosclerosis and cardiovascular disease.

Dimension Vista™ Apolipoprotein Calibrator
Apolipoprotein Calibrator is an *in vitro* diagnostic product for the calibration of the Apolipoprotein A-I (APOAI) and Apolipoprotein B (APOB) methods on the Dimension Vista® System.

Dimension Vista™ Apolipoprotein Control
Apolipoprotein Control is an assayed intralaboratory quality control for assessment of precision and analytical bias in determination of apolipoprotein A-I (APOAI) and apolipoprotein B (APOB) on the Dimension Vista® System.

Prescription Use __X__ (Per 21 CFR 801 Subpart D)
Over-The-Counter-Use _____ (21 CFR 801)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

[illegible] Sign-Off
[illegible] of In Vitro Diagnostic Device
[illegible] and Safety
K063608